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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/532,677	06/15/2005	Hiroshi Hirai	2005_0629A	4373

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WASHINGTON, DC 20006-1021

EXAMINER

TRUONG, TAMTHOM NGO

ART UNIT	PAPER NUMBER
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1624

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
31 DAYS	04/20/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/532,677	HIRAI ET AL.	
	Examiner	Art Unit	
	Tamthom N. Truong	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 January 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) 8 and 18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-7 and 9-17 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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Applicant's election with traverse of Group 2 in the reply of 1-12-07 is acknowledged. The traversal is on the ground that the compounds of 4 groups only differ by the cyclic linker B. However, different size of ring B, and different heteroatoms represented by X would distinct the core structure of one group from the next. Clearly formula I represents an improper Markush group.

Thus, the restriction is deemed proper, and therefore, made FINAL.

Group 2 was indicated with further restriction, and so, it is restricted as below. Note, claims 12 and 13 are now included in Group 2 as they were inadvertently omitted.

Claims 8 and 18 are withdrawn as being drawn to the non-elected subject matter.

Claims 1-7 and 9-17 are considered herein.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group 2a, claim(s) 1-7 and 9-17 (in part), drawn to compounds of formula I with the following substituents:

X is NH;

B is B₁(B₁')-B₂(B₂')-B₃(B₃')-B₄(B₄')-B₅(B₅');

Pharmaceutical composition thereof, and method of inhibiting Cdk using said compounds.

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Group 2b, claim(s) 1-6, 9-11 and 13-16 (in part), drawn to compounds of formula I with the following substituents:

X is S;

B is B₁(B₁')-B₂(B₂')-B₃(B₃')-B₄(B₄')-B₅(B₅');

Pharmaceutical composition thereof, and method of inhibiting Cdk using said compounds.

Group 2c, claim(s) 1-6, 9-11 and 14-16 (in part), drawn to compounds of formula I with the following substituents:

X is O;

B is B₁(B₁')-B₂(B₂')-B₃(B₃')-B₄(B₄')-B₅(B₅');

Pharmaceutical composition thereof, and method of inhibiting Cdk using said compounds.

Group 2d, claim(s) 1-6, 9-11 and 14-16 (in part), drawn to compounds of formula I with the following substituents:

X is CH₂;

B is B₁(B₁')-B₂(B₂')-B₃(B₃')-B₄(B₄')-B₅(B₅');

Pharmaceutical composition thereof, and method of inhibiting Cdk using said compounds.

Inventions of Groups 1-4 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are distinct from each other by variables X and B.

The inventions of Groups 1-4 have a common core of *quinoxalinone*, which does not sufficiently define the invention, and is not a contribution to the art. It is the combination of variables B, and variable X of the benzo fused 5-membered ring, and the quinoxalinone that gives compounds of each group their unique physical, chemical properties and biological activities. Depending on what they represent, the claimed formula would have different

structure. Thus, a reference anticipated or rendered obvious compounds of one group would not do so to those of other groups. Therefore, a separate search is required for each group.

Note, variables X and B constitute different combination of rings for formula I, and makes formula I an improper Markush group.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required. Also, because the inventions have acquired a separate status in the art due to their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Under 35 U.S.C. 372(b)(2), "international applications designating but not originating in, the United States...the Commissioner may cause the question of unity of invention to be reexamined under section 121 of this title..." Thus, as discussed above, the instant invention clearly lacks unity according to PCT 13.2. Accordingly, restriction under 35 U.S.C. 121 and 372 is deemed necessary.

Due to the complicated structure of the combination of rings containing X and B and formula I, the restriction is presented in writing. Applicant is advised that the reply to this requirement to be complete must include (i) an election of an invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically

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point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tamthom N. Truong whose telephone number is 571-272-0676. The examiner can normally be reached on M, T and Th (9:00-5:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Tamthom N. Truong
Examiner
Art Unit 1624



KAHSAY HABTE
PRIMARY EXAMINER

for James Wilson

4-12-07